REMARKS

Reconsideration of the rejections made in the mentioned Office Action is respectfully requested.

Claim 9 has been amended to even more appropriately reflect the specification. It is now indicated that the anion X is one derived from an acid which is effective to open the mentioned methylene group. This phraseology and concept are clearly recited in the specification at page 8, lines 5-8. It is made clear that the chlorine atom in the contaminant depicted on page 8 is derived from a ring opening attack accomplished by the involved acid, in the particular case being discussed in the specification, HCl. It is unambiguous to a skilled worker that if a different acid is used which is effective for ring opening, a different anion, of course, will be involved such as other halides, etc.

Shulze does not render the claims obvious. This reference relates to preparation of tritiated compounds. This is true also for the cited Example 2. Such isotopically labeled compounds are prepared for various test purposes. Procedures disclosed for such isotopic preparations do not imply anything about commercially relevant preparations. In contrast, the current invention involves an unexpected and significant improvement in a commercially relevant preparation process.

Furthermore, Schulze contains not even a hint of any impurity profile which might be involved. In contrast, the specification of this application discusses specific impurity problems and even discloses specific problematic impurities. See page 8 of the application. Whereas it may be true that, once an impurity profile is known, skilled workers can more readily employ purification techniques such as HPLC to arrive at an appropriately pure compound, without such

an impurity profile it cannot be presumed that HPLC purifications can be accomplished without undue experimentation. Thus, this specification provides significant information which the reference lacks.

Patentability is especially clear for the claims of this application which specify purity amounts and for certain claims where maximum contents of specified impurities are recited.

As can be seen, the claims are not obvious over Schulze.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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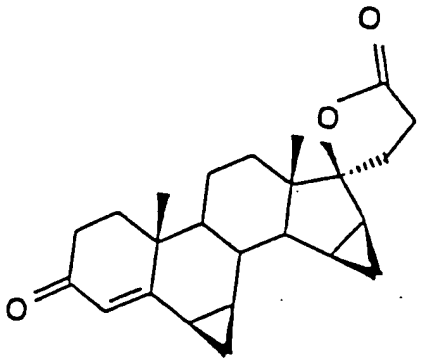
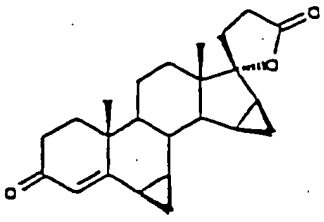
VERSION WITH MARKINGS TO SHOW CHANGES MADE

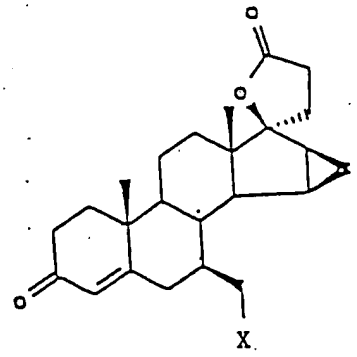
4. (Amended) 6β,7β; 15β,16β-dimethylene-3-oxo-17α-pregn-4-ene-21, 17-carbolactone, at a mean purity of ~~at least~~ greater than 98.9%.



9. (Amended) A composition comprising 6ß, 7ß; 15ß, 16ß-dimethylene-3-oxo-17α -pregn-4-ene-21, 17-carbolactone of claim 4, a pharmaceutically acceptable carrier, and less then 0.2% by weight of said compound of the contaminants



and



wherein X is an anion of an acid which is effective to open said 6β, 7β-methylene group.